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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,773	01/08/2002	Steffen Leonhardt	7194	6318

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,773

Applicant(s)

LEONHARDT, STEFFEN

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,9 and 12-19 is/are rejected.
- 7) ☒ Claim(s) 2,4-8,10 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally elected for the following reasons. In the Office Action mailed on 3/7/2003, the Applicant was required to elect a species of invention for examination. These species included: (1) Group I is drawn to an apparatus with a cleansing device which comprises a controllable actuator which frees or wipes clear a light emission orifice and (2) Group II is drawn to an apparatus with a cleansing device which comprises a controllable ultrasonic generator which emits ultrasonic waves when activated. The Applicant elected Group I in Response filed on 7/1/2003. It is clear from the specification (page 7, lines 1-26 of the specification) that the species encompassing the "controllable actuator" is distinctly different from the species encompassing the "controllable ultrasonic generator" (page 7, line 27 to page 8, line 2 of the specification). The specification makes clear that a "controllable actuator" wipes the light emission orifice by using a mechanical apparatus, such as a wiper or piston. (page 7, lines 1-26 of the specification). Any attempt by the Applicant to contend that the "ultrasonic generator" is encompassed in the term "controllable actuator" would contradict the teachings of the Applicant's disclosure. (page 7, line 1 to page 8, line 2 of the specification).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 9, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,623,248 to Sperinde in view of Japanese Patent Application Publication 08-029699 to Kitagawa. In regard to claim 1, it is noted that the limitation "for measuring human blood sugar level" is merely "intended use" language, which cannot be relied upon to define over the combination since the combination discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2nd 1647. Sperinde teaches an apparatus that includes a catheter 24, a light source 4, a measurement point 30 inside a blood vessel, a detector 32, and a computer unit 74. (Fig. 4 of Sperinde). Sperinde does not teach the use of a cleansing device for removing tissue particles deposited from the blood. Kitagawa teaches that apparatuses that are inserted into a body fluid have the potential of debris adhering to the apparatus. (paragraph 0005 of Kitagawa). Kitagawa teaches a cleansing device that includes an actuator in the form of a wiper 6a for removing debris that would interfere with optical measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cleansing

apparatus of Kitagawa in the device of Sperinde since debris from inside a body fluid may adhere to the measurement apparatus, which causes interference with optical measurements. In regard to claim 3, a motor runs the wiper 6a. (paragraph 0016 of Kitagawa). In regard to claim 9, a switch connected to the motor activates the wiper, which is considered means of an electrical control line. In regard to claim 12, the energy for controlling the wiper is supplied by mechanical means since the wiper is connected to a motor, which is connected to a switch. In regard to claim 13, reflection measurements are disclosed. (column 1, lines 55-64 of Sperinde).

4. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,623,248 to Sperinde in view of Japanese Patent Application Publication 08-029699 to Kitagawa as applied to claim 1, and further in view of U.S. Patent 5,333,609 to Bedingham et al. The combination does not teach the use of a biocompatible material. The combination teaches the use of a catheter but does not teach what material to use for the catheter. It is well known in the art to clad the catheter with a biocompatible material. (column 5, lines 66-68 of Bedingham et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the biocompatible material since material selection is required and Bedingham et al. teaches one such material.

5. Claims 1 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,763,655 to Wirtzfeld et al. in view of U.S. Patent 4,623,248 to Sperinde,

and further in view of Japanese Patent Application Publication 08-029699 to Kitagawa. In regard to claim 1, it is noted that the limitation "for measuring human blood sugar level" is merely "intended use" language, which cannot be relied upon to define over the combination since the combination discloses all of the claimed elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. Wirtzfeld teaches a frequency-controlled heart pacemaker, which includes an implanted pacemaker housing and a blood oxygen sensor. (Fig. 1 of Wirtzfeld et al.). Wirtzfeld et al. disclosed schematically a blood oxygen sensor that includes a light source 12, a detector 13, and a processor 10. (Fig. 1 of Wirtzfeld et al.). Wirtzfeld et al. does not teach a specific physical embodiment of the blood oxygen sensor. Sperinde teaches an apparatus that includes a catheter 24, a light source 4, a measurement point 30 inside a blood vessel, a detector 32, and a computer unit 74. (Fig. 4 of Sperinde). The use of a catheter would fulfill the requirements of providing a physical embodiment of a blood oxygen sensor as set forth in Wirtzfeld et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the catheter for the blood oxygen sensor as disclosed by Sperinde since Wirtzfeld et al. requires a physical embodiment of a blood oxygen sensor and Sperinde teaches one such physical embodiment. The combination does not teach the use of a cleansing device for removing tissue particles deposited from the blood. Kitagawa teaches that apparatuses that are inserted into a body fluid have the potential of debris adhering to the apparatus. (paragraph 0005 of Kitagawa). Kitagawa teaches a cleansing device that includes an actuator in the form of a wiper 6a for removing debris that would interfere with optical

measurements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the cleansing apparatus of Kitagawa in the combination since debris from inside a body fluid may adhere to the measurement apparatus, which causes interference with optical measurements. In regard to claim 16, the combination teaches processing unit with a power supply in the implant. (Fig. 3 of Wirtzfeld et al.). The combination also teaches that the light source and detector are also located in the housing with the processing unit. (Fig. 4 of Sperinde).

6. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,763,655 to Wirtzfeld et al. in view of U.S. Patent 4,623,248 to Sperinde, and further in view of Japanese Patent Application Publication 08-029699 to Kitagawa as applied to claim 16, and further in view of U.S. Patent 5,404,877 to Nolan et al. The combination does not teach the use of a telemetry unit. Nolan et al. teaches that it is well known in the art to use telemetric units in pacemakers so that physicians can program the pacemaker. (column 22, lines 16-23 of Nolan et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a telemetric device as disclosed by Nolan et al. so that physicians can program the pacemaker. In regard to claim 18, Nolan teaches that induction coils are used as antennas to transmit the data. (Fig. 1 of Nolan et al.). In regard to claim 19, capacitors are charged in telemetric device 68 when the device received energy in the form of data transmission. (Fig. 1 of Nolan et al.).

Response to Arguments

7. Applicant's arguments filed 3/8/2004 have been fully considered but they are not persuasive. In regard to the 103 rejections of claims 1, 3, 9, and 12-13 over Sperinde/Kitagawa combination, the Applicant first contends that there is no teaching or suggestion for modifying Sperinde with the wiper of Kitagawa. As pointed out in the previous Office Action mailed on 9/8/2003, the Examiner provided the suggestion for modifying Sperinde because the use of the cleansing apparatus of Kitagawa in the device of Sperinde would remove the debris that may adhere to the measurement apparatus, which causes interference with optical measurements. The Applicant contends that there is no suggestion that the catheter in Sperinde required a cleaning device. Again, the Examiner provided the suggestion for combining the Sperinde teachings with the Kitagawa teachings, i.e., the cleansing apparatus of Kitagawa in the device of Sperinde would remove the debris that may adhere to the measurement apparatus, which causes interference with optical measurements. The Applicant then contends that Kitagawa does not disclose a catheter, which is designed to be inserted in a blood vessel. This argument is unavailing because the Examiner rejected claim 1 from the combined teachings of Sperinde and Kitagawa. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regard to the 103 rejections of claims 1 and 16 over Wirtzfeld/Sperinde/Kitagawa combination, the Applicant contends that there is no suggestion or teaching to combine Sperinde with Kitagawa. The Examiner provided the suggestion to combine Wirtzfeld with Sperinde, i.e., Wirtzfeld et al. requires a physical embodiment of a blood oxygen sensor and Sperinde teaches one such physical embodiment, in the previous Office Action mailed on 9/8/2003. Also, the Examiner provided the suggestion to combine the Wirtzfeld/Sperinde combination with Kitagawa, i.e., the cleansing apparatus of Kitagawa in the combination would remove the debris that may adhere to the measurement apparatus, which causes interference with optical measurements, in the previous Office Action mailed on 9/8/2003.

Allowable Subject Matter

8. Claims 2, 4-8, 10, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 2, the prior art does not teach or suggest that the cleansing device is controllable by the computer unit. In regard to claim 4, the prior art does not teach or suggest the actuator comprising a piston which is inserted into a form-fitting opening located at the free end of the catheter and which moves between a position where it forms a seal flush with the catheter surface and a position where it fits into a

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recess located opposite the catheter surface, and that in the recessed position a light emission orifice of the at least one optical waveguide becomes free. In regard to claim 10, the prior art does not teach or suggest that the control line consists of a hydraulic or pneumatic line. In regard to claim 20, the prior art does not teach or suggest a control unit located extracorporeally for regulating human blood sugar levels, wherein the measured values are transmitted by a telemetry unit to said control unit, an extracorporeal insulin pump for injecting insulin through the peritoneum, and a regulator integrated into the control unit which controls the insulin pump subject to the measured values in such a way that the desired blood sugar level is attained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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